AN ACUTE DERMAL TOXICITY STUDY OF
IN ALBINO
RABBITS

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This summary of data and conclusions is based upon the sample received. Additional studies may be required as specific uses and formulations are developed or if process changes occur.

## ABSTRACT

An acute dermal toxicity study was designed to either establish a non-lethal dose level of 2,000 mg/kg body weight or to determine the $LD_{50}$ of in albino rabbits. The procedure followed fulfills the requirements outlined in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981. A single dose of 2,000 mg/kg body weight was applied to the intact skin of ten rabbits (5/sex). One male rabbit died on day 6 of the study. The necropsy of this animal showed consolidation of the left lung due to microbial infection and the death therefore was not considered compound related. Slight body weight loss was observed on day 7 in two of the rabbits. No behavioral changes were noted during the 14-day study period. Terminal sacrifice of animals did not reveal any compound related gross pathological alterations in the tissues and organs examined. On the basis of the data presented in this report, it is concluded that is essentially non-toxic when applied on an acute basis to the intact skin of rabbits and a single dose of this material at a dose level of 2,000 mg/kg body weight is considered as a non-lethal dose according to O.E.C.D. definition.



*Amine siloxane hydrolyzate

Distribution

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TEST MATERIAL

A clear, colorless liquid identified as was submitted to the Toxicology Department for the determination of acute dermal toxicity and an assessment of the industrial handling hazards associated with acute exposure. The procedure for testing this material was based on methods recommended in the "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," adopted in May, 1981.

METHOD

Ten young albino rabbits (5/sex) of the New Zealand white strain (obtained from Langshaw Farms, Augusta, Michigan), weighing approximately 2.0 - 3.0 kg were employed for this study. Animals were kept under observation for seven days prior to initiation of the study and only suitable animals were used for the experiment. All rabbits were housed individually in clean, stainless steel cages in a temperature, humidity, and light controlled room. The animals were maintained on a standard PURINA® Rabbit Chow and fresh water ad libitum. Each rabbit was identified by an individual permanent ear tag.

Twenty-four hours prior to dermal application, the hair of each rabbit was closely clipped from the dorsal body surface area of the trunk with electric clippers. Just prior to treatment, each rabbit was weighed.

A single dose of 2.0 g/kg was uniformly applied to the clipped skin (approximately 10% of the total body surface area) of each of the rabbits. The test material was held in close contact for twenty-four hours with a porous gauze dressing and by wrapping the animal in a semiocclusive fashion with a cotton cloth bandage taped to the hair. After a twenty-four hour exposure period, the bandages were removed and the skins were washed with tap water. Animals were observed frequently after dosing and twice daily during the weekdays over a 14-day period for signs of toxicity and behavioral abnormalities. All rabbits were weighed prior to initiation, and at 7 and 14 days post test material application. A complete gross pathological examination was performed on all rabbits at the termination of the study.

RESULTS

No behavioral changes were noted as a result of treating rabbits dermally with 2,000 mg/kg body weight of One male rabbit died on day 6 of the study. The death of this rabbit was attributed to a lung infection not related to the application of the compound. Slight reduction in body weights was observed in two of the rabbits on day 7. This reduction in body weights, only in two rabbits, was not considered in any way related to the application of the compound. Terminal sacrifice of the animals did not reveal any gross pathological alterations in the tissues and organs examined. On the basis of these observations, the dermal $LD_{50}$ of was considered to be greater than 2,000 mg/kg in albino rabbits and therefore no additional testing is required according to "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report."

CONCLUSIONS

Under the conditions of this test, a dose of 2,000 mg/kg of body weight of is essentially non-toxic when applied on an acute basis to the intact skin of rabbits and is considered as a non-lethal dose according to O.E.C.D. definition.

REFERENCES

1) "O.E.C.D. Short-Term and Long-Term Toxicology Groups Final Report," published in December, 1979, and adopted in May, 1981.

2) DeVries, C. R., and Siddiqui, W. H., 1983. "An Acute Dermal Irritation Study with in Albino Rabbits". Series No.

This Report constituted of pages 1-6, and Table I, signed this 8th day of April, 1985.

Authors:

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QUALITY ASSURANCE STATEMENT

This report represents data generated by the Toxicology Department, This study was conducted according to EPA Toxic Substances Control; Good Laboratory Practices Regulations; 40 CFR, Part 797, Vol. 48, No. 230. The results of the report accurately reflect the data generated. All raw data is located at

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|---|---|
| Study Started: | February 6, 1985 |
| Study Completed: | February 20, 1985 |
| Date Audited: | February 6, 1985 and February 20, 1985 |
| Report Issued: | April 16, 1985 |

Date: April 8, 1985

TABLE I

Acute Dermal Toxicity of in Rabbits

MORTALITY DATA

| Condition of Skin | Sex | Dose (mg/kg) | No. Dead/No. Dosed |
|---|---|---|---|
| Intact | M | 2,000 | 1/5* |
| Intact | F | 2,000 | 0/5 |

*Death occurred due to lung infection.